Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	An Open-Label, Phase 2 Trial of Nanatinostat in Combination With Valganciclovir in Patients With Epstein-Barr Virus-Positive (EBV+) Relapsed/Refractory Lymphomas
Protocole ID	VT3996-202
ClinicalTrials.gov ID	NCT05011058
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Nanatinostat en association avec le Valganciclovir
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dre Isabelle Fleury
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Statut	Actif en recrutement
Date d'activation	06-01-2022
But étude	Patients with EBV-associated lymphomas have inferior outcomes with standard-of-care therapies compared to those with EBV-negative disease. Nanatinostat is a selective class I HDAC inhibitor which induces EBV lytic phase protein generation, activating (val)ganciclovir to its cytotoxic form. This open-label, multicenter, multinational, single-arm, basket study employs a Simon's 2-stage design to allow termination of enrollment into cohorts where treatment appears futile, and will include the following cohorts of patients with EBV+ relapsed/refractory lymphomas.This is an open-label, multicenter, multinational single-arm, Phase 2 basket design study, utilizing Simon's 2-stage design. The study will include 7 cohorts of patients with the following EBV+ relapsed/refractory lymphomas: • EBV+ diffuse large B-cell lymphoma (DLBCL, NOS) • Extranodal NK/T-cell lymphoma (ENKTL) • Peripheral T-cell lymphoma (PTCL), including PTCL-NOS and AITL • Hodgkin lymphoma (HL) • Post-transplant lymphoproliferative disorder (PTLD) • HIV-associated lymphomas (Plasmablastic, Burkitt, Hodgkin, DLBCL) • EBV+ lymphoproliferative disorders other than the above
Critères d'éligibilité	• EBV+ relapsed/refractory lymphoma following 2 or more prior systemic therapies • EBV+ DLBCL, NOS: Must have received at least one course of an anti-CD20 immunotherapy, and at least one course of anthracycline-based chemotherapy • PTLD: Must have received immunotherapy with an anti-CD20 agent. • Hodgkin lymphoma: Must have received at least one course of anthracycline-based chemotherapy. Patients with classical Hodgkin lymphoma should have failed or be ineligible for an anti-PD-1 agent and CD30-directed therapy. • For extranodal NK/T-cell lymphoma patients only: Relapsed/refractory disease following 1 or more prior systemic therapies. Patients must have failed an asparaginase-containing regimen. • No available therapies in the opinion of the Investigator

	• Not eligible for high-dose chemotherapy with allogeneic/autologous stem cell transplantation or CAR-T therapy • Measurable disease per Lugano 2007 • ECOG performance status 0, 1, 2 • Adequate bone marrow function
Critères d'exclusion	• Presence or history of CNS involvement by lymphoma • Systemic anticancer therapy or CAR-T within 21 days • Antibody (anticancer) agents within 28 days • Less than 60 days from prior autologous hematopoietic stem cell or solid organ transplant • Less than 90 days from prior allogeneic transplant. • Daily corticosteroids (≥20 mg of prednisone or equivalent) within week prior to Cycle 1 Day 1 • Inability to take oral medication, malabsorption syndrome or any other gastrointestinal condition (nausea, diarrhea, vomiting) that may impact the absorption of nanatinostat and valganciclovir. • Active infection requiring systemic therapy (excluding viral upper respiratory tract infections).